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Are the recorded data of flash glucose monitoring systems influenced by radiological examinations?

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Abstract

The FreeStyle Libre Pro® flash glucose monitoring system is easy to use in diabetes care. However, the influence of radiological examination on recorded data has not been reported. The sensor should be removed prior to examinations involving strong magnetic or electromagnetic radiation. In the present study, it was assumed that radiological examination was performed without removing the FreeStyle Libre Pro® sensor in certain unanticipated situations. We researched the integrity of data recorded by the FreeStyle Libre Pro® system following exposure to chest X-rays, computed tomography (CT), radiotherapy (RT), and magnetic resonance imaging (MRI). Fifty sensors were exposed to chest X-ray, CT, RT, and MRI (1.5-T and 3.0-T), and the recorded data were compared with those obtained before the tests. Ten sensors were included in each group. There were no unread data or errors when the sensors were read. No change was observed before and after the examination for all tests.

Keywords Flash glucose monitoring systems · Recorded data · Radiological examinations · Magnetic resonance imaging · X-ray

1 Introduction

The FreeStyle Libre Pro® (Abbott Japan Co., Ltd., Tokyo, Japan) flash glucose monitoring (FGM) system is easy to use in diabetes care. Glucose data (measured at 15-min intervals) can be recorded by the disposable sensor for up to 14 days [1]. The sensor is placed subcutaneously on the posterior surface of the upper arm to measure glucose content in the interstitial fluid [2] (Fig. 1). This system avoids the inconvenience of self-monitoring of blood glucose, thus facilitating the optimization of glycemia; this can help reduce the risk of complications and improve the quality of life in patients with diabetes [3]. Moreover, this system has accuracy similar to that of continuous glucose monitoring systems [2]. The characteristics of glucose exposure, variability, stability, and hypoglycemia risk and occurrence were quickly obtained via an automated ambulatory glucose profile [1]. Furthermore, FGM systems effectively reduce glucose variability [4].

The system's instruction manual cautioned that the sensor should be removed prior to examinations involving strong magnetic or electromagnetic radiation, including X-ray, magnetic resonance imaging (MRI), or computed

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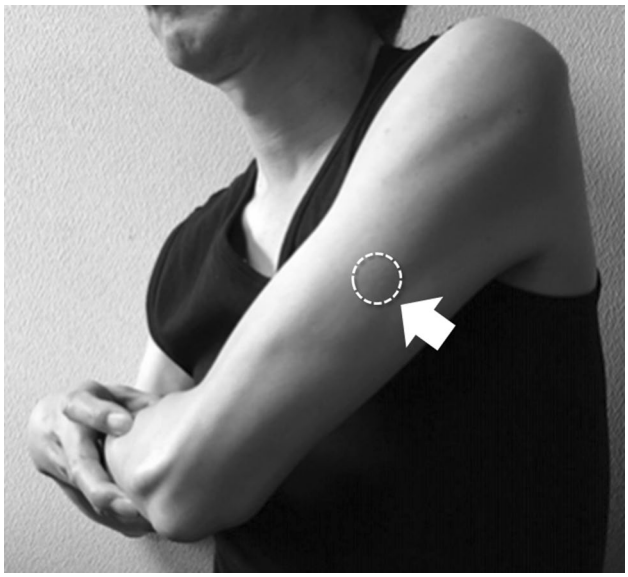

Fig. 1 The position of the sensor

tomography (CT) [5], and that a new sensor should be applied after the examination.

If patients or staff did not remove the sensor before an examination, is the recorded data influenced? If recorded data that requires long examination and processing time is lost or destroyed, it not only poses a problem to medical treatment but also increases the patient's medical expenses and requires increased care as the lost data needs to be measured again. However, if the data are not influenced, it should not be evaluated again. The influence of radiological examination on recorded data has not been reported.

Therefore, we researched the integrity of data recorded by the FreeStyle Libre Pro® system following exposure to chest X-ray, CT, radiotherapy (RT), or MRI.

In the present study, it was assumed that radiological examination was performed without removing the sensor of the FreeStyle Libre Pro® in certain unanticipated situations.

2 Materials and methods

This study was approved by the Ethics Committee of Osaka Red Cross Hospital (Osaka, Japan). For this type of retrospective study, formal consent is not required.

Fifty FreeStyle Libre Pro® sensors with data recorded for 14 days were used. These sensors were exposed to chest X-ray, CT, RT, or MRI (1.5-T and 3.0-T), and the recorded data were compared with those obtained before the tests. Ten sensors were included in each group.

2.1 Chest X-ray

Chest X-ray, which was assumed to involve chest examination, was performed using RadSpeed Detector Pro (Shimadzu Corporation, Kyoto, Japan) with CALNEO HC SQ (17 × 17-inch, Fujifilm Corporation, Tokyo, Japan) and a PBU-2-type chest phantom (Kyoto Kagaku Co., Ltd, Kyoto, Japan).

The sensors were placed at the center of phantom instead of the posterior surface of the subcutaneous upper arm for convenience because our focus was to appropriately irradiate the device with primary X-ray; moreover, the chest phantom had no arms.

Standard conditions for chest examinations used at Osaka Red Cross Hospital (source–film distance, 200 cm; field, 35 × 43 cm; tube voltage, 120 kV; tube current, 160 mA; and exposure time, 20 ms) were applied. The sensor was set at the center of the chest phantom to correspond to the center of exposure (Fig. 2a), and it was exposed to X-rays 10 times.

The skin surface absorbed dose was 0.152 mGy, as calculated based on the following equation:

$$\text{Skin surface absorbed dose (mGy)} = C\,(\text{kv}) \times \text{mAs} \times 1/\,\text{FSD}^2$$

where C is the correction coefficient by the tube voltage, mAs is the tube current time product, and FSD is the focus-skin distance.

2.2 CT

A 64-multidetector row CT system (Discovery CT750HD-A; GE Healthcare, Milwaukee, WI, USA) was used with the following parameters: rotation time, 0.5 s; beam collimation, 64 × 0.625 mm; section thickness and intersection gap, 5.0 mm; helical pitch (beam pitch), 0.984:1; table movement, 78.75 mm/s; scan field of view, 500 mm; voltage, 120 kV; tube current, 100–550 mA; image reconstruction, 350 mm; and display field of view, 500 mm. These scan protocols were designed for chest examination. An N-1 chest phantom (Kyoto Kagaku Co., Ltd, Kyoto, Japan) was used. The sensor was used five times on each side of the shoulder of the phantom to account for the influence of tube rotation (Fig. 2b, b′, b″). FreeStyle Libre Pro® sensors were used one at a time, and the phantom was set at the center of the gantry. The skin surface absorbed dose was 13.5 mGy as calculated using nanoDot® dosimeter (NAGASE LANDAUER, Ltd, Ibaraki, Japan).

2.3 RT

An RT system, Cliniac iX (Varian Medical Systems, Palo Alto, CT, USA), with an I'mrt Phantom (IBA Dosimetry, Bartlett, TN, USA), P-Si semiconductor detector EDD-2

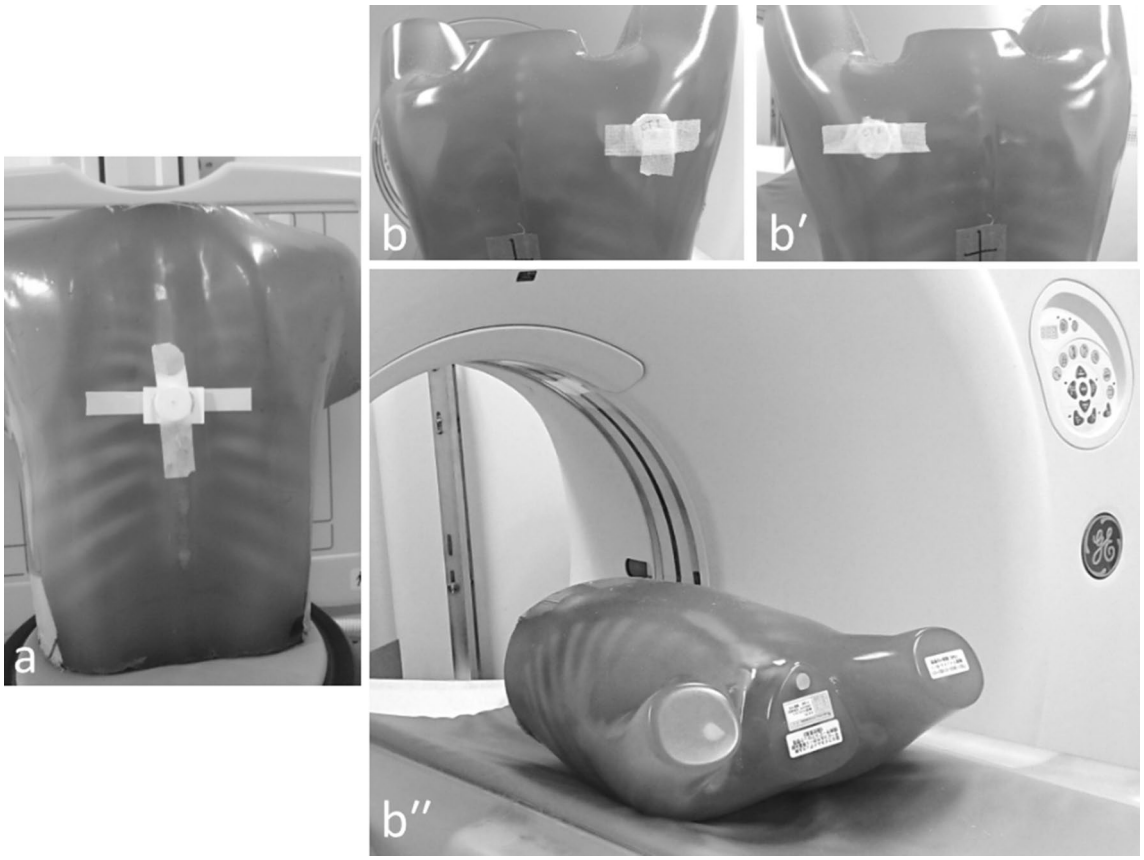

Fig. 2 The setting of the sensor; chest X-ray (**a**) and computed tomography (sensor set to right side (**b**); left side (**b′**); and set on the table (**b″**)

p-Sa Photon detector (Scanditronix Medical, Uppsala, Sweden), and Fingertip type 30,013 standard chamber (PTW Freiburg, Freiburg, Germany) was used with the following parameters: source–axis distance, 100 cm; field, 10 × 10 cm; tube voltage, 10 MV; exposure dose, 20 Gy; and dose rate, 600 MU/min.

The FreeStyle Libre Pro® sensor was set at the center of the phantom, i.e., at the iso-center (Fig. 3a, a′). Considering the correction factor, the MU value was calculated to an actual irradiation dose of 20 Gy.

2.4 MRI

MRI with a high specific absorption rate (SAR) sequence was performed using a 1.5-T MRI unit (Achieva, Q body coil; Philips Medical Systems, Best, Netherlands) with the following parameters: balanced turbo field echo (TFE) sequence; SAR, 4.0 w/kg, first level; B_{1+}rms, 4.53 μT; peripheral nerve stimulation (PNS), 95%, first level; dB/dt, 155.5 T/S; repetition time (TR)/echo time (TE), 1.97 ms/0.98 ms; TFE factor, 256; matrix, 128; slice, 20; slice thickness, 5 mm; scan time, 27.1 s × 67, 30 min 3 s (total scan time).

High SAR sequence MRI was performed using a 3.0-T MRI unit (Ingenia, anterior and posterior coil; Philips Medical Systems, Best, Netherlands) with the following parameters: balanced TFE sequence; SAR, 3.2 w/kg, first level; B_{1+} rms, 2.29 μT; PNS, 92%, first level; dB/dt, 107.0 T/S; TR/TE, 1.90 ms/0.93 ms; TFE factor, 128; matrix, 128; slice, 20; slice thickness, 5 mm; scan time, 21.7 s × 80 (dynamic mode), 30.1 min (total scan time). These were the highest SAR values for each MRI unit.

The FreeStyle Libre Pro® sensor was set at the center of the phantom (3.3685 g/L $NiCl_2$-$6H_2O$ and 2.4 g/L NaCl; 15.5 × 38.0 × 15.5 cm) (Fig. 3b, b′). The phantom was set at the center of the magnet using adhesive tape and scanned. Ten sensors were used in total.

2.5 Statistical analysis

The recorded data were compared before and after exposure in all tests. The mean and standard deviation (SD) were calculated, and the Pearson's Chi-square test was used for statistical analyses (EZR v. 3.4.1 [6]). Statistical significance was determined as $P < 0.05$.

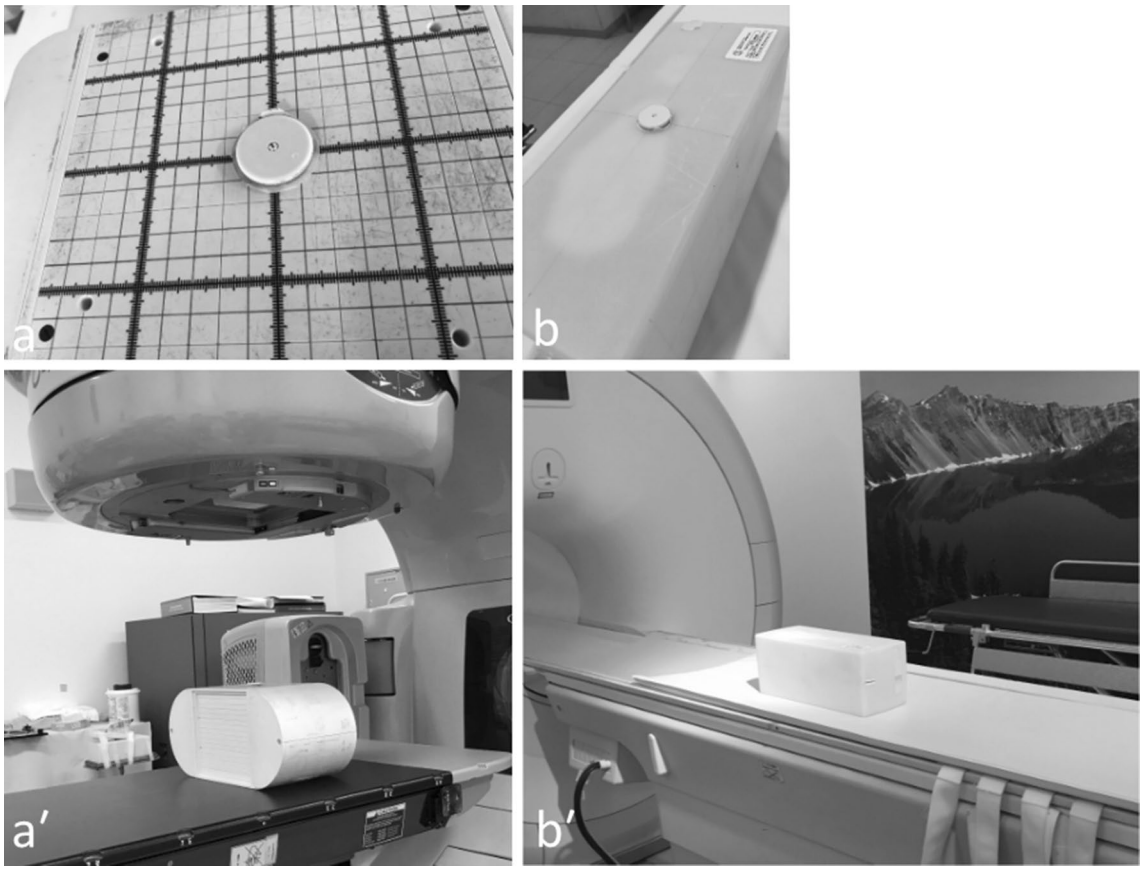

Fig. 3 The setting of the sensor; radiotherapy (**a, a′**), and magnetic resonance imaging (**b, b′**)

3 Results

Notably, there were no unread data or errors when the sensors were read. The mean and SD are shown in Table 1. The absence of difference in the data before and after the examinations is shown in Table 2. No change was observed before and after the examination for any test.

4 Discussion

The recorded data were not influenced by chest X-ray, CT, RT, or MRI. Thus, a new measurement and additional medical expense may not be needed if a FreeStyle Libre Pro® sensor is exposed to medical radiation. We believe that the present study covered all daily uses of the aforementioned sensor based on the higher radiation doses and higher SARs than those typically used; therefore, the recorded data were not damaged during routine studies.

Although the recorded data were not affected by any test, several limitations must be mentioned.

First, when the sensor was in the imaging or irradiation area, the image quality or radiation dose distribution might have been influenced. However, the influence of this factor was not investigated. Second, we could not evaluate the performance of the sensor regarding whether it remained functional after exposure to radiation, necessitating further study.

Third, we did not assess the safety for the human body. Implanted cardiac pacemakers are influenced by RT [7]. The device may have been exposed to radiofrequency heat [8], thereby leading to malfunctions [9–11] in MRI. Radiofrequency induces a current that flows through the pacemaker lead circuit, which damages the cardiac tissue [8], and could lead to the occurrence of unintended cardiac stimulation [12, 13]. The influence of these factors was not investigated in the present study.

Although the data recorded by the sensor were not affected by exposure to radiation, the sensor should be removed before certain examinations because of its potential effect on image quality, dose distribution, and heat dissipation.

Diabetes is a serious issue in our country [14], and the control of blood glucose level is important for successful treatment. We considered that the FGM system would be able to control the blood glucose level in patients with diabetes. However, it remains a major concern that

Table 1 Result of the calculation of the mean and standard deviation between before and after chest X-ray, computed tomography, radiotherapy, and magnetic resonance imaging (1.5-T and 3.0-T)

	XP		CT		RT		MRI (1.5T)		MRI (3.0T)	
Sample no.	Before	After	Before	After	Before	After	Before	After	Before	After
1	127.5 ± 38.1	127.5 ± 38.1	132.4 ± 35.4	132.4 ± 35.4	131.3 ± 51.4	131.3 ± 51.4	122.4 ± 32.7	122.4 ± 32.7	245.7 ± 102.7	245.7 ± 102.7
2	161.9 ± 40.5	161.9 ± 40.5	141.9 ± 59.9	141.9 ± 59.9	141.9 ± 37.7	141.9 ± 37.7	137.3 ± 48.5	137.3 ± 48.5	213.8 ± 52.3	213.8 ± 52.3
3	150.6 ± 44.1	150.6 ± 44.1	150.3 ± 65.4	150.3 ± 65.4	77.5 ± 33.8	77.5 ± 33.8	178.8 ± 65.2	178.8 ± 65.2	144.3 ± 63.5	144.3 ± 63.5
4	168.0 ± 84.3	168.0 ± 84.3	238.4 ± 64.6	238.4 ± 64.6	125.4 ± 45.2	125.4 ± 45.2	182.1 ± 75.8	182.1 ± 75.8	129.8 ± 36.6	129.8 ± 36.6
5	148.3 ± 56.6	148.3 ± 56.6	175.1 ± 84.0	175.1 ± 84.0	152.6 ± 49.0	152.6 ± 49.0	195.7 ± 65.4	195.7 ± 65.4	173.6 ± 73.4	173.6 ± 73.4
6	167.2 ± 91.5	167.2 ± 91.5	200.8 ± 83.0	200.8 ± 83.0	109.0 ± 26.8	109.0 ± 26.8	197.9 ± 60.8	197.9 ± 60.8	119.0 ± 49.4	119.0 ± 49.4
7	164.2 ± 52.3	164.2 ± 52.3	130.6 ± 40.8	130.6 ± 40.8	127.2 ± 42.1	127.2 ± 42.1	145.2 ± 65.9	145.2 ± 65.9	96.4 ± 17.1	96.4 ± 17.1
8	176.7 ± 49.7	176.7 ± 49.7	220.6 ± 94.5	220.6 ± 94.5	229.3 ± 121.2	229.3 ± 121.2	209.9 ± 74.0	209.9 ± 74.0	138.6 ± 42.6	138.6 ± 42.6
9	176.8 ± 72.9	176.8 ± 72.9	147.5 ± 40.3	147.5 ± 40.3	194.1 ± 61.0	194.1 ± 61.0	283.7 ± 128.7	283.7 ± 128.7	145.0 ± 19.1	145.0 ± 19.1
10	169.4 ± 54.9	169.4 ± 54.9	233.1 ± 98.9	233.1 ± 98.9	199.9 ± 56.7	199.9 ± 56.7	163.5 ± 66.1	163.5 ± 66.1	130.7 ± 51.2	130.7 ± 51.2

Mean ± standard deviation

XP chest X-ray, *CT* computed tomography, *RT* radio therapy, *MRI* magnetic resonance imaging

Table 2 Cross-tabulation table of the Pearson's Chi-square test

Observed frequency				Expected frequency			
Modality	Difference		Total	Modality	Difference		Total
	Yes	No			Yes	No	
XP	0	10	10	XP	0	10	10
CT	0	10	10	CT	0	10	10
RT	0	10	10	RT	0	10	10
MRI (1.5T)	0	10	10	MRI (1.5T)	0	10	10
MRI (3.0T)	0	10	10	MRI (3.0T)	0	10	10
Total	0	50	50	Total	0	50	50

Pearson's Chi-square test

XP chest X-ray, *CT* computed tomography, *RT* radiotherapy, *MRI* magnetic resonance imaging

patients tend to undergo routine examinations with the sensor still attached. Hence, doctor and hospital staff should be advised to remove the sensor from the patient while conducting such examinations; moreover, patients must be educated regarding the removal of the sensor prior to examinations. If, however, radiological examinations were conducted without the removal of the sensor, hospital staff and the manufacturers of the FGM system should be aware of the effect on the recorded data. The present study involved basic research; further studies are warranted to gain better insights because we are unable to conclude that the FreeStyle Libre Pro® sensor does not need to be removed prior to examination in the present study.

In conclusion, the data recorded by the FreeStyle Libre Pro® were not influenced despite radiological examinations—chest X-ray, CT, RT, or MRI—being performed without removing its sensor.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the Ethics Committee of Osaka Red Cross Hospital (Osaka, Japan). For this type of retrospective study, formal consent is not required. All procedures performed in studies were in accordance with the ethical standards of the Institutional Review Board.

Statement of human or animal right This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Distiller LA, Cranston I, Mazze R. First clinical experience with retrospective flash glucose monitoring (FGM) analysis in South Africa: characterizing glycemic control with ambulatory glucose profile. J Diabetes Sci Technol. 2016;10:1294–302.
2. Ólafsdóttir AF, Attvall S, Sandgren U, Dahlqvist S, Pivodic A, Skrtic S, Theodorsson E, Lind M. A clinical trial of the accuracy and treatment experience of the flash glucose monitor freestyle libre in adults with type 1 diabetes. Diabetes Technol Ther. 2017;19:164–72.
3. Ajjan RA. How can we realize the clinical benefits of continuous glucose monitoring? Diabetes Technol Ther. 2017;19:27–36.
4. Slattery D, Choudhary P. Clinical use of continuous glucose monitoring in adults with type 1 diabetes. Diabetes Technol Ther. 2017;19:55–61.
5. FreeStyle. Libre Pro flash glucose monitoring system: operator's manual. Alameda (CA): Abbott Diabetes Care Inc.; Sep 23, 2016. http://www.accessdata.fda.gov/cdrh_docs/pdf15/P150021C.pdf. Accessed 15 Feb 2017.
6. Kanda Y. Investigation of the freely available easy-to-use software 'EZR' for medical statistics. Bone Marrow Transplant. 2013;48:452–8.
7. Ferrara T, Baiotto B, Malinverni G, Caria N, Garibaldi E, Barboni G, Stasi M, Gabriele P. Irradiation of pacemakers and cardiodefibrillators in patients submitted to radiotherapy: a clinical experience. Tumori. 2010;96:76–83.
8. Walton C, Gergely S, Economides AP. Platinum pacemaker electrodes: origins and effects of the electrode-tissue interface impedance. Pacing Clin Electrophysiol. 1987;10:87–99.
9. Sheibelhofer W, Glogar D, Probst P, Milczoch J, Kaindl F. Induction of ventricular tachycardia by pacemaker programming. Pacing Electrophysiol. 1982;5:587–92.
10. Naehle CP, Meyer C, Thomas D, Remerie S, Krautmacher C, Litt H, Luechinger R, Fimmers R, Schild H, Sommer T. Safety of brain 3-T MR imaging with transmit-receive head coil in patients with cardiac pacemakers: pilot prospective study with 51 examinations. Radiology. 2008;249:991–1001.
11. Nazarian S, Hansford R, Roguin A, Goldsher D, Zviman MM, Lardo AC, Caffo BS, Frick KD, Kraut MA, Kamel IR, Calkins H, Berger RD, Bluemke DA, Halperin HR. A prospective evaluation of a protocol for magnetic resonance imaging of patients with implanted cardiac devices. Ann Intern Med. 2011;155:415–24.
12. Hayes DL, Homes DR Jr, Gray JE. Effect of 1.5 T nuclear magnetic resonance imaging on implanted permanent pacemakers. J Am Coll Cardiol. 1987;10:782–6.
13. Fontaine JM, Mohamed FB, Gottlieb C, Callans DJ, Marchlinski FE. Rapid ventricular pacing in a patient undergoing magnetic resonance imaging. Pacing Clin Electrophysiol. 1998;21:1336–9.
14. Ministry of Health, Labor and Welfare Diabetes Homepage. https://www.mhlw.go.jp/www1/topics/kenko21_11/b7.html, Accessed 20 Nov 2018.